K101024
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## 5. 510(k) SUMMARY

JAN - 6 2011

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| Submitter: | Suzuken Co., Ltd.<br>8 Higashikataha-machi Higashi-ku<br>Nagoya, Aichi, Japan 461-0015 |
| Contact Person: | Mr. Shuji Funahashi<br>Senior Manager, Kenz Product Development R&D Section<br>TEL: +81-52-701-4402<br>FAX: +81-52-703-0914<br>s.funahashi@suzuken.co.jp |
| Date Prepared: | December 7, 2010 |
| Trade Name: | Kenz® Cardy302Max Digital Holter System |
| Common Name: | Digital Ambulatory Holter Recorder |
| Classification Name: | Electrocardiograph, Ambulatory (without analysis)<br>Medical Magnetic Tape Recorder |
| Predicate Device: | SEER Light Extend (K050731) |
| Device Description: | The Cardy302Max Compact Digital Holter System is designed to acquire ambulatory 2 or 3 channels of ECG signal from the chest surface of pediatric or adult patients for up to 48 hours. The device stores the acquired ECG data on its removable memory card.<br>The Cardy Controller02 downloads patient demographic information into the Cardy302Max Compact Digital Holter Recorder and allows the user to check the signal quality of the ECG data at hookup time. At the end of recording, the ECG data can be transferred to the controller by removing the SD memory card from the recorder and installing it into the Cardy Controller02. |
| Statement of Intended Use: | The Cardy302Max Compact Digital Holter Recorder System is intended to acquire ambulatory 2 or 3 channel ECG signals from the chest surface of pediatric or adult patients. The device stores this data along with patient demographic information onto a removable SD memory card.<br>The Cardy302Max Compact Digital Holter Recorder System is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or medical professional's facility.<br>The Cardy302Max Compact Digital Holter Recorder System does not perform any analysis of the ECG data.<br>The Cardy302Max Compact Digital Holter Recorder System is not intended for use on patients weighing less than 10 kg. |

Summary of Technological Characteristics:

The proposed Compact Digital Holter Recorder System employs the same functional scientific technology as the predicate device SEER Light Extend Compact Digital Holter System (K050731).

Summary of Test Data:

Testing reports demonstrate successful outcomes to compliance testing to the voluntary standards listed below. These successful outcomes indicate that the Cardy302Max meets the (1) general requirements for safety, (2) electromagnetic compatibility, and (3) particular requirements for safety, including essential performance, for ambulatory electrocardiographic systems for medical electrical equipment.

(1) IEC 60601-1
(2) IEC 60601-1-2
(3) IEC 60601-2-47

The following quality assurance measures were applied to the development of this device.

1. Risk Analysis
2. Requirement Reviews
3. Design Reviews
4. Testing on Unit Level (Module Verification)
5. Integration Testing (System Verification)
6. Final Acceptance testing (Validation)
7. Performance Testing
8. Safety Testing
9. Environmental Testing

Independent water ingress testing was successfully conducted in accordance with IEC 60529: 2001 for IPX5, X8H for the Cardy302Max device.

Software verification and validation testing was conducted, which demonstrated that all modes and functions of the Cardy302Max device operated as designed and in accordance with the indications for use.

Conclusion:

The documented design output, device labeling, and test results demonstrate that the Cardy302Max Compact Digital Holter System is equivalent to the predicate device regarding safety, effectiveness, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Suzuken Co, Ltd.
c/o Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Suite 280
Richardson, TX 75080

JAN - 6 2011

Re: K101024
Trade/Device Name: Cardy302Max Digital Holter System
Regulation Number: 21 CFR 870.2800
Regulation Name: Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: MWJ
Dated: December 7, 2010
Received: December 8, 2010

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

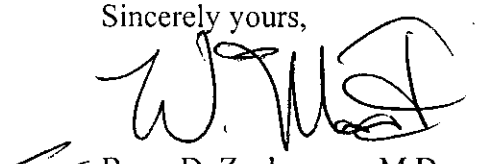
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

JAN - 6 2011

510(k) Number: K101024



Device Name: Cardy302Max Compact Digital Holter Recorder System

Indications for Use:

The Cardy302Max Compact Digital Holter Recorder System is intended to acquire ambulatory 2 or 3 channel ECG signals from the chest surface of pediatric or adult patients. The device stored this data along with patient demographic information onto a removable SD memory card.

The Cardy302Max Compact Digital Holter Recorder System is intended to be used by trained operators under the direct supervision of a licensed healthcare practitioner in a hospital or medical professional's facility.

The Cardy302Max Compact Digital Holter Recorder System does not perform any analysis of the ECG data.

The Cardy302Max Compact Digital Holter Recorder System is not intended for use on patients weighing less than 10 kg.

Prescription Use____X____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101024